

REMARKS

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 102; and claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 103. Applicants respectfully submit that the rejections are improper for the reasons set forth below.

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 102. More specifically, claims 11-13, 16-19 and 21-25 are rejected in view of U.S. Patent No. 5,578,302 ("*302 Patent*"); and claims 11-14, 16-19 and 21-26 are rejected in view of U.S. Patent No. 5,494,664 ("*664 Patent*"). The Patent Office essentially asserts that either of these references discloses each and every feature of the claimed invention.

Applicants believe that the anticipation rejections are improper. Of the pending claims, claims 11, 19 and 23 are the sole independent claims. Claim 11 recites a method for the treatment or prophylaxis of calcium deficiencies in a mammal having or at risk of calcium deficiency; claim 19 recites a method for increasing absorption of calcium from a diet; and claim 23 recites a method for improving the absorption of calcium in a mammal. Independent claims 11, 19 and 23 each include, in part, the step of administering to the mammal a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

In contrast, the '*302 Patent* or the '*664 Patent* are deficient with respect to the claimed invention. Indeed, the Patent Office even admits that the '*302 Patent* or the '*664 Patent* are silent with respect to particular effects as claimed, such as treatment or prophylaxis of mineral deficiencies including calcium in a mammal or for improving absorption of minerals including calcium from the diet. See, Office Action, p. 8. In this regard, the Patent Office has relied on three references in addition to the '*302 Patent* or the '*664 Patent* in support of the rejection of the claims under 35 U.S.C. § 103.

Of course, the Court of Appeals for the Federal Circuit has held that "when more than one reference is required to establish unpatentability of the claimed invention, anticipation under § 102 cannot be found, and validity is determined in terms of § 103." *Continental Can Co. USA v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1748 (Fed. Cir. 1991). Thus, it is clearly improper for the Patent Office to reject the claimed invention under 35 U.S.C. § 102 where, on the other hand, the Patent Office cites to multiple references in addition to the '302 Patent or the '664 Patent to support the obviousness rejection regarding the claimed invention. Based on at least this reason, the anticipation rejections should be withdrawn.

In any event, the '302 Patent or the '664 Patent are clearly deficient with respect to the claimed invention. For example, each of the '302 Patent and the '664 Patent relates to general health benefits. In the '644 Patent, for example, the clear emphasis relates to a particular property of the genus *Bifidobacterium* to exclude pathogenic bacteria from intestinal cells. Indeed, pathogenic bacteria are deleterious bacteria that have the capacity to invade or infect the intestines of a mammal and in this way cause disease. The *Bifidobacterium* as disclosed in the '644 Patent act to compete with and finally supersede the harmful pathogenic bacteria that may invade human intestines. In the '302 Patent, the primary emphasis relates to an anti-gastritis and/or anti-ulcer agent which is capable of displacing pathogenic bacteria from intestinal and/or gastric cells. See, '302 Patent, Col. 1, lines 34-36. Thus, clearly, neither of these references discloses mineral absorption in general, let alone calcium absorption in particular.

In contrast, the claimed invention relates to a method for the treatment or prophylaxis of calcium deficiencies in a mammal (claim 11); a method for increasing absorption of calcium from a diet (claim 19); and a method for improving the absorption of calcium in a mammal (claim 23). These claimed features should be given patentable weight and as such are clearly distinguishable from the cited art.

Further, each of the independent claims are limited to administering the nutritional composition to a mammal that requires increased calcium absorption wherein the claimed nutritional composition includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal. This provides direct contact of the *Lactobacillus* bacteria with the intestinal cells, thus facilitating the absorption of calcium by the intestinal cells.

Indeed, there are a number of reasons why a mammal would require increased mineral absorption, such as for pregnancy or old age as disclosed in the Specification. In contrast, the '664 Patent is particularly directed to mammals that require an anti-diarrhoeic (see, '664 Patent, column 1, lines 35-46); and the '302 Patent is merely directed to patients that require an anti-ulcer agent and/or anti-gastritis agent as previously discussed.

Moreover, nowhere do either of the '302 Patent or the '664 Patent disclose or suggest the methods of the claimed invention that require administering the nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

Indeed, Applicants have demonstrated that the *Lactobacillus* bacteria administered in a living state can facilitate the absorption of minerals in the mammal. In Example 1 of the Specification, for example, a human colon cell line is exposed to living *Lactobacilli* in an in vitro model that demonstrates the beneficial effects of the claimed invention. Again, nowhere do either of the '302 Patent or the '664 Patent disclose or suggest that the direct interaction between intestinal cells and living *Lactobacilli* can facilitate or improve the absorption of minerals by the intestinal cells as required by the claimed invention.

Nor do either of the cited references anticipate the claimed invention under the principles of inherency contrary to the Patent Office's position. Of course, "[i]nherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a

given set of circumstances is not sufficient." In re *Oelrich*, 212 USPQ 323, 326 (C.C.P.A. 1981) (quoting *Hansgirs v. Kemmer*, 40 USPQ2nd 665, 667 (C.C.P.A. 939)). Indeed, the cited references are completely silent with respect to the absorption of minerals, namely calcium, as even admitted by the Examiner. As previously discussed, the '664 Patent, for example, relates to the competitive exclusion of pathogenic bacteria and not how to enhance absorption of calcium in intestines as claimed and as demonstrated by Applicants as previously discussed. Based on at least these reasons, Applicants believe that the cited references are clearly distinguishable from the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejections with respect to the claimed invention be withdrawn.

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 103 as being unpatentable over the '302 Patent or the '664 Patent and further in view of *Yaeshima*, *Yoshida* and *Sellars*. The Patent Office primarily relies on the '302 Patent or the '664 Patent and thus relies on the combined teachings of the remaining cited references to remedy the deficiencies of the '302 Patent or the '664 Patent. Applicants respectfully submit that this rejection is improper for the reasons set forth below.

At the outset, the primary references, namely, the '302 Patent or the '664 Patent, are clearly deficient with respect to the claimed invention for substantially the same reasons as discussed above. Indeed, the '302 Patent or the '664 Patent are silent with respect to particular effects as claimed such as treatment or prophylaxis of mineral deficiencies including calcium in a mammal or for improving absorption of minerals including calcium from the diet as even admitted by the Patent Office. Again, the primary focus of the '664 Patent relates to the competitive exclusion of pathogenic bacteria and not how to facilitate the absorption of calcium.

As previously discussed, the '302 Patent relates to an anti-gastritis and/or anti-ulcer agent which is capable of displacing pathogenic bacteria from intestinal and/or gastric cells.

Further, Applicants do not believe that the Patent Office can rely solely on the combined teachings of the remaining references to remedy the deficiencies of either the '302 Patent or the '664 Patent. As previously discussed, the independent claims require that the *Lactobacillus* bacteria is administered in a living state to the intestines of the mammal. Applicants have surprisingly shown that living *Lactobacilli*, in direct interaction with intestinal cells, are able to facilitate or improve the absorption of minerals by intestinal cells. See, Specification, page 9, line 35 to page 10, line 2. This is clearly not linked to the ability of acidifying the experimental medium as indicated in the Specification on page 9, at lines 26-29. In this regard, the methods of the claimed invention are not directed to the effects of a fermented medium, or, the product that is produced by the bacteria, but to the direct interaction between living *Lactobacilli* and intestinal cells that can facilitate or improve the absorption of minerals (i.e., calcium) by the intestinal cells.

In contrast, Applicants believe that, at most, the cited art merely suggests metabolites produced by lactobacilli and which are present in fermented dairy products may have a desirable effect on mineral absorption. This is a clear teaching away from the present invention where it is found that the immediate action of the living *Lactobacillus* bacteria in the intestines leads to an increase of mineral absorption.

Indeed, *Sellars*, for example, discloses that the presence of minute quantities of lactic acid can influence the rate of absorbed minerals. One of the reasons for increased growth in animals fed fermented products was increased bio-availability. Further, *Sellars* discloses that, for example, lactose, lactic acid and vitamin D all increased absorption of minerals. See, *Sellars*, page 102. Lactic acid is a metabolite of fermenting *Lactobacillus*.

Further, in *Yoshida*, this reference merely compares germ-free, namely, gnotobiotic mice (e.g., devoid of bacteria, even in the intestines) to mice that were fed with bacteria from the human intestines. The result of the *Yoshida* study indicated that gnotobiotic mice did not suffer deleterious effects with respect to mineral absorption. This clearly suggest that the presence or absence of bacteria has no effect on mineral absorption.

Nor does *Yaeshima*, when added to the combination of references, disclose or suggest the claimed invention. First, it must be pointed out that *Yaeshima* does not mention lactobacillus but a bacteria species of a non-related gender. In this regard, *Yaeshima* discloses *Bifidobacterium longum* together with lactulose. Further, no gender, but a species-specific effect is merely described (*B. longum*). Perhaps, most importantly, it was found that *B. longum* alone did not lead to a significant increase in calcium absorption but, that lactulose must be present (see Figure 13). In this regard, *Yaeshima*, at most, disclosed a lactose-dependent effect on calcium absorption. In view of same, Applicants believe that the secondary references clearly fail to disclose or suggest to the extent that they effectively teach away from direct interaction of living *lactobacillus* bacteria in the intestines, thus enhancing the absorption of calcium as required by the claimed invention.

What the Patent Office has done is to rely on "hindsight reasoning" to support the obviousness rejections. This is clearly improper. Again, the primary references are clearly deficient with respect to the claimed invention. Indeed, the primary focus of the '664 Patent relates to competitive exclusion of pathogenic bacteria and not how to enhance the absorption of calcium in the intestines. Again, the '302 Patent relates to an anti-gastritis and/or anti-ulcer agent which is capable of displacing pathogenic bacteria from intestinal and/or gastric cells. Moreover, the secondary references effectively teach away from the claimed invention as previously discussed.

Indeed, Applicants have demonstrated that even without fermented (acidified) dairy product lactobacilli directly and solely causes the intestinal cells to absorb calcium at a higher rate. Thus, one skilled in the art, viewing the combined teaching of the secondary references, would not be inclined to modify the primary references, alone or in combination, to arrive at the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

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